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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,813	07/22/2003	Winthrop D. Childers	10008113-4	7780

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EXAMINER	
KOCH, GEORGE R	

ART UNIT	PAPER NUMBER
1734	

DATE MAILED: 07/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/625,813	CHILDERS, WINTHROP D.	
	Examiner	Art Unit	
	George R. Koch III	1734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-26,31 and 32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-26,31 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Terminal Disclaimer

1. The terminal disclaimer filed on 5/6/2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patents issuing from application 10/777,449; 10/777,448 or 10/375,794 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 12, 19-21, and 31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 of copending Application No. 11/017,163.

The limitations of claim 12 are obvious but not identical to the limitations of claim 1 of US 11/017,163. The reservoir corresponds to the reservoir, the drop generator with the ejector, and the controllers is an obvious variation of the electronic circuitry. The pharmaceutical receiving medium of the instant claims is merely a definition of the intended use and does not materially distinguish the claim structure.

As to claim 30, the apparatus of claim 1 of US 11/017,163 is capable of applying to a dose form.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 12, 13, 16, 19-25 and 31-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Wirch (US 5,881,716).

As to claim 12, Wirch discloses an apparatus for manufacturing a pharmaceutical dose onto a pharmaceutical receiving medium, the apparatus comprising a reservoir capable of containing one fluid pharmaceutical component, a fluid drop generator (item 8) fluidically coupled to the reservoir (item 5); and a control (columns 2-3) activating the fluid drop generator to eject a variably selected quantity of the pharmaceutical

component onto the medium. The exact dose amount can be selected by an operator (abstract; Figure 5, column 1, lines 10, 21, 34, 44).

As to claim 13, Wirch discloses that the liquid reservoir is replaceable (column 2, line 28).

As to claim 16, Wirch discloses that the system can operate by remote control (see column 2, line 22).

As to claim 19, Wirch discloses a control unit which is an information storage element carrier on the reservoir and fluid drop generator, the information storage element electrically connectable to the control and providing communicable information to the control of at least one parameter of the pharmaceutical component and fluid drop generator (column 2, line 59 to column 3, line 48).

As to claim 20, Wirch discloses a replaceable cartridge (see column 2, lines 26-28) capable of functioning as claimed, the cartridge comprising a reservoir (item 5) and a fluid drop generator (item 8) capable of being used as claimed.

As to claim 21, Wirch discloses a control unit which is an information storage element carrier on the reservoir and fluid drop generator, the information storage element electrically connectable to the control and providing communicable information to the control of at least one parameter of the pharmaceutical component and fluid drop generator (column 2, line 59 to column 3, line 48).

As to claim 22, the control unit of Wirch is capable of storing the identity of the pharmaceutical component.

As to claim 23, Wirch discloses that the fluid drop generator can be integrally coupled to the reservoir (see Figure 1).

As to claim 24, Wirch discloses that the information storage elements specify the number of drops to be dispensed (see column 3, lines 35-40, which recite "droplets per time unit")).

As to claim 25, Wirch discloses that the fluid drop generator can be integrally coupled to the reservoir (see Figure 1).

As to claims 31 and 32, the apparatus of Wirch is capable of apply to a dose form.

6. Claims 12-15, 18-26 and 31-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Voges (US 5,894,841).

As to claim 12, Voges discloses an apparatus for manufacturing a pharmaceutical dose onto a pharmaceutical receiving medium, the apparatus comprising a reservoir capable of containing one fluid pharmaceutical component, a fluid drop generator (item 14) fluidically coupled to the reservoir (item 10); and a control (item 16) activating the fluid drop generator to eject a variably selected quantity of the pharmaceutical component onto the medium. The exact dose amount can be selected by an operator.

As to claim 13, the liquid reservoir is inherently replaceable, and also discloses that the components can be changed (see column 10, lines 43-63, which recites that the parts are replaceable).

As to claim 14, Voges discloses that the dispenser can be provided with a plurality of cartridges or reservoirs (column 11, line 67), each which can hold a different component.

As to claim 18, Voges discloses that the dispenser can be provided with a plurality of chambers (column 12, lines 1-2) each which can hold a different component.

As to claim 19, Voges discloses a control unit which is an information storage element carrier on the reservoir and fluid drop generator, the information storage element electrically connectable to the control and providing communicable information to the control of at least one parameter of the pharmaceutical component and fluid drop generator (column 11, lines 1-60).

As to claim 20, Voges discloses a replaceable cartridge (see column 10, lines 43-63, which recites that the parts are replaceable) capable of functioning as claimed, the cartridge comprising a reservoir (item 10) and a fluid drop generator (item 14) capable of being used as claimed.

As to claim 21, Voges discloses a control unit which is an information storage element carrier on the reservoir and fluid drop generator, the information storage element electrically connectable to the control and providing communicable information

to the control of at least one parameter of the pharmaceutical component and fluid drop generator (column 11, lines 1-60).

As to claim 22, the control unit of Voges is capable of storing the identity of the pharmaceutical component.

As to claim 23, Voges discloses that the fluid drop generator can be integrally coupled to the reservoir (see Figure 1 and 2).

As to claim 24, Voges discloses that the information storage elements specify the number of drops to be dispensed (see column 12, line 7, which discloses "successive medications in a dose").

As to claim 25, Voges discloses that the fluid drop generator can be integrally coupled to the reservoir (see Figure 1 and 2).

As to claim 26, Voges discloses that the dispenser can be provided with a plurality of chambers (column 12, lines 1-2) each which can hold a different component.

As to claims 31 and 32, the apparatus of Voges is capable of apply to a dose form.

7. Claims 12-13, 17, 19-25 and 31-232 are rejected under 35 U.S.C. 102(b) as being anticipated by Moldavsky (US 6,061,608).

As to claim 12, Moldavsky discloses an apparatus for capable of being used for manufacturing a pharmaceutical dose onto a pharmaceutical receiving medium, the apparatus comprising a reservoir (i.e., pump 25 in which the liquid 17 is stored) capable

of containing one fluid pharmaceutical component, a fluid drop generator (item 23) fluidically coupled to the reservoir; and a control (item 22 and 30) capable of activating the fluid drop generator to eject a variably selected quantity of the pharmaceutical component onto the medium.

As to claim 13, the apparatus of Moldavsky is inherently replaceable.

As to claim 17, Moldavsky discloses a weight detector (item 21, and see column 3 and 4) for detecting and outputting signals corresponding to the weight of the substrate (which can be the claimed substrate) after the liquid (which can be the component) is dispensed onto the substrate.

As to claim 19, Moldvasky discloses a control (items 22 and 30) which functions as the claimed information storage element.

As to claim 20, Moldavsky as applied above discloses the reservoir and fluid drop generator. Furthermore, the apparatus of Moldavsky is inherently replaceable.

As to claims 21-22, the control of Moldavsky (items 22 and 30) functions as the information storage element and is capable of performing all of the claimed steps.

As to claim 23, the drop generator of Moldavsky is integrally coupled to the reservoir (i.e., pump - see Figure 1).

As to claims 24, the control of Moldavsky (items 22 and 30) functions as the information storage element and is capable of performing all of the claimed steps.

As to claim 25, the drop generator of Moldavsky is integrally coupled to the reservoir (i.e., pump - see Figure 1).

As to claims 31 and 32, the apparatus of Moldavsky is capable of apply to a dose form.

8. Claims 12-13, 19-26 and 31-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Burns (US 5,284,133)

As to claim 12, Burns discloses an apparatus for capable of being used for manufacturing a pharmaceutical dose onto a pharmaceutical receiving medium, the apparatus comprising a reservoir (item 10) capable of containing one fluid pharmaceutical component, a fluid drop generator (nebulizer - recited in column 10, lines 35-51) fluidically coupled to the reservoir; and a control (Figure 2, and see column 9) capable of activating the fluid drop generator to eject a variably selected quantity of the pharmaceutical component onto the medium.

As to claim 13, the apparatus of Burns is replaceable (see column 9, lines 1-8, which disclose placing multiple canisters).

As to claim 19, Burns discloses a control (items 22 and 30) and chip (item 25) which functions as the claimed information storage element.

As to claim 20, Burns as applied above discloses the reservoir and fluid drop generator. Furthermore, the apparatus of Burns is replaceable.

As to claims 21-22, the control of Burns (Figure 2) functions as the information storage element and is capable of performing all of the claimed steps.

As to claim 23, the drop generator of Burns is integrally coupled to the reservoir (Figure 4a).

As to claims 24, the control of Burns (Figure 2) functions as the information storage element and is capable of performing all of the claimed steps.

As to claim 25, the drop generator of Burns is integrally coupled to the reservoir (Figure 4a).

As to claim 26, Burns discloses that the chip stores a parameter identifying the pharmaceutical component (see column 4, lines 60-63).

As to claims 31 and 32, the apparatus of Burns is capable of apply to a dose form.

Claim Rejections - 35 USC § 103

9. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Voges (US 5,894,841) as applied to claim 14 above.

As to claim 14, Voges discloses that the dispenser can be provided with a plurality of cartridges or reservoirs (column 11, line 67), each which can hold a different component. Furthermore, as to claim 15, Voges discloses that the fluid generator can have more than one fluid drop generators (see column 10, line 51).

Voges fails to teach that the different fluid drop generators are used for the different medications. However, official notice is taken that it would have been well known and conventional to have linked the multiple drop generators with individual cartridges or reservoirs. One in the art would immediately recognize that connecting the reservoirs to the generators would enable the storage of multiple pharmaceuticals in

one device, and multiple dosing regimes, without cross-contamination. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have utilized various generators separately connected to the reservoirs in order to reduce cross-contamination.

10. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over either of Wirch (5,881,716) or Voges (US 5,894,841) as applied to claim 12 above, and further in view of Moldavsky (US Patent 6,061,608).

Neither Wirch nor Voges discloses a weight detector for detecting and outputting signals corresponding to the weight of the pharmaceutical receiving medium after the one pharmaceutical component has been dispensed onto the pharmaceutical receiving medium.

Moldavsky discloses a weight detector(item 21) for detecting and outputting signals corresponding to the weight of the pharmaceutical receiving medium after the one pharmaceutical component has been dispensed onto the pharmaceutical receiving medium. Moldavsky discloses that such weight control allows for improvements in the volumetric accuracy and repeatability of the dispensing process (see column 1, lines59-62). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have utilized such weight controls in the inventions of Wirch or Voges in order to achieve volumetric accuracy and repeatability.

Response to Arguments

11. Applicant's arguments filed 5/6/2005 have been fully considered but they are not persuasive.

12. All of the arguments (including the traversal of the Obviousness type Double Patenting rejection base based on 11/017,163) are based on the argument that the that references do not disclose a pharmaceutical receiving medium.

13. In response to applicant's argument that the references do not disclose a pharmaceutical receiving medium, it is note that any substrate which receives a pharmaceutical is inherently a pharmaceutical receiving medium.

14. In response to applicant's argument that the references do not disclose a pharmaceutical receiving medium, and assuming in arguendo that the phrase "pharmaceutical receiving medium" excludes the substrates of Wirch, Voges, Moldavsky, or Burns, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). The pharmaceutical receiving medium is not part of the apparatus and does not patentably distinguish from the prior art.

Conclusion

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Koch III whose telephone number is (571) 272-1230 (TDD only). If the applicant cannot make a direct TDD-to-TDD call, the applicant can communicate by calling the Federal Relay Service at 1-866-377-8642 and giving the operator the above TDD number. The examiner can normally be reached on M-Th 10-7.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Fiorilla can be reached on (571) 272-1187. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

George R. Koch III
Patent Examiner
Art Unit 1734

GRK
7/19/2005